

**FOR PUBLICATION  
UNITED STATES COURT OF APPEALS  
FOR THE NINTH CIRCUIT**

UNITED STATES OF AMERICA,  
Plaintiff-Appellee,

v.  
JACK WATKINS,  
Defendant-Appellant.

UNITED STATES OF AMERICA,  
Plaintiff-Appellee,

v.  
CAP TAB NUTRITIONAL  
FORMULATINGAND MANUFACTURING  
INC.,  
Defendant-Appellant.

Appeal from the United States District Court  
for the Southern District of California  
Napoleon A. Jones, District Judge, Presiding

Argued and Submitted  
September 14, 2001--Pasadena, California

Filed January 29, 2002

Before: Ferdinand F. Fernandez, Andrew J. Kleinfeld, and  
M. Margaret McKeown, Circuit Judges.

Opinion by Judge McKeown;  
Dissent by Judge Fernandez

No. 00-50656

D.C. No.  
CR-99-00024-J

No. 00-50682

D.C. No.  
CR-99-00024-NAJ

OPINION





## **COUNSEL**

Eugene G. Iredale, San Diego, California, for the defendant-appellant.

Melanie K. Pierson, Assistant United States Attorney, United States Attorney's Office, San Diego, California, for the plaintiff-appellee.

## **OPINION**

McKEOWN, Circuit Judge:

Section 303 of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 333(a)(2), imposes felony liability for misbranding "with the intent to defraud or mislead." The question presented is whether this provision requires proof of materiality. We hold that materiality must be proven as an element of the offense under either a theory of intent to defraud or a theory of intent to mislead.

## **BACKGROUND**

Jack Watkins is the president and majority owner of Cap-Tab Nutritional Formulating and Manufacturing, Inc., a company that manufactures vitamins and nutritional supplements (collectively, "Watkins"). The subject of this appeal arises from Watkins' conditional guilty plea under the FDCA following a nineteen-count indictment. The indictment charged Watkins with conspiracy, mail fraud, wire fraud, and felony misbranding. According to the indictment, Watkins manufactured nutritional supplements by purposefully omitting, substituting, or using lesser amounts of certain ingredients. Specifically, the government alleged that one product, "C3D," did not contain acetyl L-carnitine as labeled. Rather, it contained L-carnitine, which was one of approximately six ingredients in the product. The government also claimed that two other products, "Neurotein" and "Energy," did not contain chromium picolinate as labeled. Rather, they contained chromium polyniconate, which was one of approximately eight ingredients in Neurotein and one of approximately fifteen ingredients in Energy. The indictment further charged that Watkins concealed these facts, knowing that his actions constituted false and misleading labeling.

Before trial, the government filed a motion in limine, moving to exclude evidence that the substitutions were not mate-

rial. Watkins responded by arguing that proof of materiality was required for conviction under the felony misbranding provisions of § 333(a)(2). Watkins also claimed that he believed that his substitution of ingredients did not constitute a material difference, despite admitting that he knew of the disparity between the labels and the actual ingredients. The district court granted the government's motion to exclude evidence of materiality. The same day, pursuant to a plea agreement, Watkins pled guilty to the three felony misbranding counts. The plea was conditioned upon the preservation of Watkins' right to appeal, under Federal Rule of Criminal Procedure 11(a)(2), the issue of "whether materiality must be proven for a conviction for the offense of a felony charge of misbranding."

The district court sentenced Watkins to five years supervised probation and imposed a \$5,000 fine. Cap-Tab and Watkins appealed separately; we have consolidated their appeals. The sole legal issue, which we address de novo, is whether materiality constitutes an element of felony misbranding under the FDCA. See United States v. Steffen, 251 F.3d 1273, 1275 (9th Cir. 2001); United States v. Douglass, 780 F.2d 1472, 1475 (9th Cir. 1986).

## **DISCUSSION**

### **I. FDCA OVERVIEW**

The Food, Drug, and Cosmetic Act is a public welfare statute that imposes "the highest standard of care on distributors." Smith v. California, 361 U.S. 147, 152 (1959). It was enacted to enable purchasers to make intelligent choices, and, to that end, "[m]isbranding was one of the chief evils Congress sought to stop." United States v. 45/194 Kg. Drums of Pure Vegetable Oil, 961 F.2d 808, 812 (9th Cir. 1992). The misbranding provision prohibits "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded." 21 U.S.C. § 331(a). "A food shall be deemed to be mis-

branded . . . [i]f . . . its labeling is false or misleading in any particular." 21 U.S.C. § 343(a)(1).

The FDCA provides two tiers of liability for misbranding violations under § 331(a). The misdemeanor provision imposes criminal liability in the form of imprisonment, fines, or both. See 21 U.S.C. § 333(a)(1) ("Any person who violates [§ 331(a)(1)] shall be imprisoned for not more than one year or fined not more than \$1,000, or both."). An article may be misbranded pursuant to the misdemeanor provision "without any conscious fraud at all," thus creating a form of strict criminal liability. United States v. Dotterweich, 320 U.S. 277, 281 (1943) (quoting United States v. Johnson, 221 U.S. 488, 497 (1911)). Felony misbranding, on the other hand, requires a showing that the defendant acted "with intent to defraud or mislead":

Notwithstanding the provisions of paragraph (1), if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than \$10,000 or both.

21 U.S.C. § 333(a)(2) (emphasis added). Thus, felony liability for misbranding requires an additional mens rea element that is absent from the broader-reaching misdemeanor provision. See United States v. Mitcheltree, 940 F.2d 1329, 1347 (10th Cir. 1991) (felony liability under § 333(a)(2) requires proof that defendant "consciously sought to mislead " authorities). The question we consider in this case is to what degree this additional element circumscribes felony liability for misbranding offenses.

## **II. FELONY LIABILITY FOR MISBRANDING REQUIRES PROOF OF MATERIALITY**

Watkins admits that he knew the labels on his nutritional supplements misrepresented the ingredients actually in the

product. Nonetheless, he argues that knowledge of falsity alone is not sufficient for conviction under § 333(a)(2). Watkins urges instead that "intent to defraud or mislead" means (1) the misrepresentation would have a material effect on any decision to buy or consume the product, or (2) the person who makes the misrepresentation has reason to believe that the misstatement would induce the reliance of others in making those decisions. Thus, Watkins argues on appeal that the district court erred in excluding evidence that he believed there was no material difference between the ingredients listed on the label and those actually in the product, and that buyers and consumers would perceive no such difference in choosing his product. The government responds that absent an explicit statutory requirement of "materiality," the intent element for § 333(a)(2) is satisfied by simply proving knowledge of falsity. We disagree with the government's overly-broad reading of this provision.

#### **A. INTENT TO DEFRAUD**

Our first charge is to divine the meaning of "intend to defraud" under § 333(a)(2). We are mindful of the rule that a court should not read words into a statute that are not there. See Aronsen v. Crown Zellerbach, 662 F.2d 584, 590 (9th Cir. 1981) ("It is consistent with the general principle of statutory construction that a court should not add language to an unambiguous statute absent a manifest error in drafting or unresolvable inconsistency."); see also SUTHERLAND STAT CONST § 47.38. We do not do so. Rather, by examining the settled meaning of "intent to defraud," we conclude that this phrase requires materiality. Our conclusion is compelled by the Supreme Court's recent teaching in Neder v. United States, 527 U.S. 1 (1999).

In Neder, the Court addressed whether a "scheme or artifice to defraud" under the federal mail, wire, and bank fraud statutes requires material falsehoods. Observing that "none of the fraud statutes defines the phrase 'scheme or artifice to



defraud,' or even mentions materiality," the Court concluded that "based solely on a `natural reading of the full text,' materiality would not be an element of the fraud statutes." 527 U.S. at 20-21 (citations omitted). The Court's analysis, however, did not end with this literal reading of the statutory language. Rather, the Court continued by looking to the common-law meaning of "defraud," invoking the "well-established rule of construction that `[w]here Congress uses terms that have accumulated settled meaning under the . . . common law, a court must infer, unless the statute otherwise dictates, that Congress means to incorporate the established meaning of those terms.'" Id. at 21 (quoting Nationwide Mut. Ins. Co. v. Darden, 503 U.S. 318, 322 (1992)). Surveying the settled meaning of "fraud," the Court concluded that "the common law could not have conceived of `fraud' without proof of materiality." Neder, 527 U.S. at 22 (citations omitted). In light of this settled meaning, the Court held that it "must presume that Congress intended to incorporate materiality unless the statute otherwise dictates." Id. at 23.

In this case, the government relies primarily on the Eighth Circuit's decision in United States v. Jorgensen, 144 F.3d 550 (8th Cir. 1998), to argue that materiality is not a requirement of § 333(a)(2). In Jorgensen, the court addressed a similar criminal misbranding provision of the Federal Meat Inspection Act, 21 U.S.C. §§ 601-695, that makes misbranding a felony for any person who has an "intent to defraud." See 21 U.S.C. § 676(a). There, the court looked no further than the literal words of the statute and held that "the statutory language does not require that the false or misleading statements be `material.'" Jorgensen, 144 F.3d at 559. It reached this conclusion without examining the common-law meaning of this language. Considering this omission, we believe that the Supreme Court's subsequent decision in Neder settles the analytical framework for interpretation of "intent to defraud." In Neder, the Court noted that an analysis "based solely on a `natural reading' " of the statutory language, "does not end our inquiry." Neder, 527 U.S. at 21 (citation omitted). Rather,

the Court instructed that "a necessary second step" is examination of any settled meaning under the common law. Id. This approach is a rejection of the literal analysis employed by the Jorgenson court.

The government attempts to distinguish this case from Neder by claiming that requiring proof of materiality for prosecution under § 333(a)(2) would frustrate Congress's purpose in passing the FDCA to "insure that the goods they offer for sale to the public were safe and properly labeled." This argument ignores the broad reach of the statute. The misdemeanor provision, § 333(a)(1), covers a wide range of conduct, imposing strict liability for misbranding, and providing criminal penalties--including imprisonment--for any affirmative misrepresentations, whether knowingly false, fraudulent, or even unintentional. See United States v. Park, 421 U.S. 658, 670-71 (1975). In other words, any misbranding is a criminal offense. The increased penalties provided by § 333(a)(2) require an additional showing of an "intent to defraud or mislead," indicating Congress's intent to limit the scope of felony liability. Considering the broad applicability of the misdemeanor misbranding provision and Congress's intent to limit liability for increased penalties, requiring proof of materiality would not frustrate Congress's purpose in enacting these provisions of the FDCA to protect public health and safety.

Nor does this requirement contradict our own admonition that "Congress fully intended that the [FDCA's] coverage be as broad as its literal language indicates." Baker v. United States, 932 F.2d 813, 814 (9th Cir. 1991) (quoting United States v. Bacto-Unidisk, 394 U.S. 784, 798 (1969)). Rather, because Congress expressly required proof of an "intent to defraud" for felony liability, "we cannot infer from the absence of an express reference to materiality that Congress intended to drop that element from [§ 333(a)(2)]. On the contrary, "we must presume that Congress intended to incorporate materiality unless the statute otherwise dictates." Neder, 527 U.S. at 23 (internal quotations and citations omitted)

(emphasis in original). The FDCA's broad coverage of criminal misbranding does not otherwise dictate.

## **B. INTENT TO MISLEAD**

Although Neder compels us to understand "intent to defraud" as requiring proof of materiality, we must consider the meaning of "intend to . . . mislead" separately because courts "are to accord a meaning, if possible, to every word in a statute." Platt v. Union Pac. R. R. Co., 99 U.S. 48, 58 (1878); accord United States v. Gonzalez-Mendez, 150 F.3d 1058, 1060 (9th Cir. 1995). Our examination of the plain meaning of this phrase as well as its settled meaning under the common law lead us to conclude that an intent to mislead also requires proof of materiality. That is, regardless of any additional liability Congress intended to include with this language, one still cannot "intend to mislead" another by means of a misrepresentation without having an expectation that the recipient would actually or reasonably rely on it.

We begin our analysis with an examination of plain meaning, for "[w]here the language is plain and admits of no more than one meaning, the duty of interpretation does not arise, and the rules which are to aid doubtful meanings need no discussion." Caminetti v. United States, 242 U.S. 470, 485 (1917) (citation omitted); accord Negonsott v. Samuels, 507 U.S. 99, 104-05 (1993). To mislead is "to lead in a wrong direction or into a mistaken belief: deceive." WEBSTER'S NEW INTERNATIONAL DICTIONARY 1444 (3d ed. 1963). In turn, to deceive is "to take unawares esp. by craft or trickery . . . to cause to believe the false." Id. at 584. Both these definitions presume an effect on another party. This understanding is reinforced by the transitive nature of the verb "to mislead." Its action requires an object--in this case another party. The addition of the word "intent" underscores the relationship between the actor and the other party. Any intent to mislead presumes an expectation or purpose that another will in fact be misled.

The government would have us believe that an intent to mislead is established by showing mere knowledge of a statement's falsity by its maker. To begin as a matter of plain meaning, an "intent" to have knowledge of a statement's falsity makes little sense. Likewise, when we consider the government's proffered meaning, its reading is at once too narrow and too broad. It is too narrow because misbranding does not require a false label; a misleading label is prohibited as well. 21 U.S.C. § 352 (drug or device misbranded if "labeling false or misleading in any particular"). At the other end of the spectrum, the government's interpretation is too broad because it would impose felony liability based solely on knowledge of a false label, no matter how insignificant the falsehood. Simply put, knowledge of falsity places a top-sided focus on the actor and does not adequately encompass the effect of the intended action on the other party.

The government also argues that in the absence of a specific reference to "materiality," we should not read this concept into § 333(a)(2). It points to several other provisions in the FDCA that prohibit misleading representations or omissions that are expressly "material," thus urging us to infer congressional meaning through the absence of the term. See 21 U.S.C. § 334(a)(1)(B) (product subject to civil seizure if label "would be in a material respect misleading to the injury or damage of the purchaser or consumer"); 21 U.S.C. § 343(a)(2) (dietary supplement may be deemed misbranded if its advertising is false or misleading in material respect); 21 U.S.C. § 321(n) (in determining whether label is misleading, must take into account material omissions). None of these examples persuade us to read "intent to . . . mislead" against its plain meaning.

The structure of the statute supports the distinctions in the language used by Congress. Many statements, whether true, incomplete, or false, can be misleading even when the maker of the representation does not intend to mislead the recipient. For example, a drug is deemed misbranded "[if ] its labeling

is false or misleading in any particular." 21 U.S.C. § 352(a). In other words, a label that is misleading in any respect may result in misdemeanor liability. Section 321(a) goes on to explain that misleading labeling can include not just affirmative statements, but material omissions. The requirement of materiality functions to cabin potentially unlimited liability by imposing a more objective standard. See Restatement (Second) of Torts § 538(a) (1977) (a matter is material if "a reasonable man would attach importance to its existence or nonexistence in determining his choice of action " or "the maker of the representation knows or has reason to know" that the recipient is likely to consider "the matter as important"). Thus, when intent is irrelevant to the imposition of liability--as is the case in the FDCA provisions cited by the government above--a requirement of materiality further limits liability to those circumstances where the consequences are significant.

Even the government notes the need for limiting penalties to labeling omissions that are material because criminal misdemeanor liability otherwise would be unlimited when "the universe of what has been omitted from the label would include essentially every other word in the English language." Brief for United States 23. Imposing liability where there is an "intent to . . . mislead," on the other hand, requires no such extrinsic limiting language: whereas any statement could be potentially misleading under these other provisions without an express limitation, the only representations that will invoke felony liability are those that the maker expects, that is, intends, the recipient to rely upon. Thus, Congress had no need to include an express reference to materiality where liability is founded upon intent.

One final point of plain meaning bears mention--had Congress intended to impose felony liability, as the government suggests, simply for making knowingly false statements in labeling, then it easily could have used such language in the statute. See, e.g., 21 U.S.C. § 335b(a) (imposing civil penal-

ties for certain false statements "knowingly made or caused to be made" to officials). Instead, Congress chose to impose liability when the maker of the misrepresentation does so with the "intent to defraud or mislead." Because this language presupposes a desired effect on a third party, an effect best understood as an expectation of reliance, we conclude as a matter of plain meaning that materiality is an element of the felony misbranding offense.

Our conclusion is buttressed by the common-law interpretation of an "intent to mislead" as encompassing an expectation of reasonable reliance. Unlike fraud with its common-law history in torts as a cause of action and term of art defined by its elements, "intent to mislead" does not necessarily enjoy such a clear or distinguished pedigree. However, to the extent this phrase does have a "well-settled meaning" at common law requiring an expectation of reliance, we must examine this language "under the rule that Congress intends to incorporate the well-settled meaning of common-law terms it uses." Neder, 527 U.S. at 23; see also Nationwide Mut. Ins. Co., 503 U.S. at 322 (1992).

We begin our inquiry into the common-law meaning of "intent to mislead" by first recalling as a matter of plain meaning that the intent to mislead is synonymous with the intent to deceive. This interchangeability of terms is important here because it is established "as the usually prevailing view in the United States" that "the intent to deceive is an indispensable element" of common-law fraud, an element which requires a showing "that the representation was made with the fraudulent intent of . . . inducing persons to act upon it." 9 STEWART M. SPEISER, ET AL., THE AMERICAN LAW OF TORTS § 32:42 (1992) (emphasis added).

Several common-law jurisdictions specifically define this expectation of reliance element of fraud as the "intent to mislead." These jurisdictions have expressly distinguished this element from any requirement regarding knowledge of a

statement's falsity. See Evaluation Research Corp. v. Alequin, 439 S.E.2d 387, 390 (Va. 1994) (actionable fraud requires both a false representation "made intentionally and knowingly" as well as the "intent to mislead"); Gaines v. Preterm-Cleveland, Inc., 514 N.E.2d 709, 712 (Ohio 1987) (actionable fraud requires both a false representation made "with knowledge of its falsity" and the "intent of misleading another into relying upon it"); Zampatti v. Tradebank Int'l Franchising Corp., 508 S.E.2d 750, 758 (Ga. App. 1998) (where fraud requires knowledge of falsity as well as "the intention and purpose of deceiving the plaintiff (causing plaintiff to act or refrain from acting in reliance thereon)," court describes latter element as "the intent to mislead [plaintiff] to his detriment"); LaSalle Nat'l Bank v. Ernst & Young LLP, 2001 N.Y. Slip Op. 06659, 2001 WL 896463, \*\*5 (N.Y. App. Aug. 9, 2001) (where fraud requires knowledge of falsity and "deception," court describes latter element as the "intent to mislead the complaining party, to its detriment"); see also Hughes v. Hertz Corp., 670 So.2d 882, 888 (Ala. 1995) (describing statutory deceit as "a willful or a reckless misrepresentation" that also requires "an intent to mislead").

Returning to the government's contention that intent for purposes of liability under § 333(a)(2) is established simply by showing knowledge of falsity, we cannot ignore that this same language requires an expectation of reliance for purposes of common-law fraud. Considering that common-law jurisdictions do not equate "intent to mislead" with guilty knowledge, we cannot imagine that Congress used "intent to mislead" to simply mean knowledge of falsity. Rather, we conclude that Congress was aware of this settled meaning of "intent to mislead" as developed within the common law of fraud, and thus must infer "that Congress means to incorporate the established meaning of these terms." Neder, 527 U.S. at 21-22 (quotations and citations omitted).

## CONCLUSION

Because felony liability for misbranding requires proof of materiality, we remand this case to the district court with

instructions to allow the defendants the opportunity to withdraw their pleas. See Fed. R. Crim. P. 11(a)(2).

**REVERSED and REMANDED.**

---

FERNANDEZ, Circuit Judge, Dissenting:

I disagree with Watkins' assertion that even though he did intentionally misstate the ingredients of the nutritional substances he was selling, he was improperly convicted because the government did not have evidence to show that the misstatements were material. There can be no doubt that Watkins intended to defraud and mislead purchasers into thinking they were purchasing one item when, in fact, they were purchasing a different, cheaper item. Of course, he did so because he knew that he could improve his own profits by so euchring his victims. That is the usual reason that a person like Watkins acts as he did here. However, he argues that even if he made more money and his victims, thus, not only had less, but also had a different kind of supplement, he cannot be guilty unless materiality is shown as a separate element. That is, he cannot have committed felony food and drug fraud, or even felony misleading, without that element. I do not agree.

Watkins relies on the general rule, set forth in Neder v. United States, 527 U.S. 1, 119 S. Ct. 1827, 144 L. Ed. 2d 35 (1999), that when the word "fraud" is used, a material misrepresentation or concealment is required because it was required at common law. Id. at 20, 119 S. Ct. at 1839. In my view, the general rule is just that and no more, and this case cries out for a determination that the general rule was not what Congress had in mind. We are dealing, after all, with labeling of food and drugs. A person who buys those is entitled to know precisely what he is ingesting. It will not do to tell him that he is getting organic food, when, in fact, it is not organic. Nor will it do to tell him he is getting aspirin, when he is getting



something else which is cheaper and supposedly just as efficacious. Who knows what the health effect might be, either now or years from now. With astonishing frequency, we hear reports that even when we know what we are ingesting, it turns out that it might have a hitherto unknown effect. For example, does manufactured vitamin C found in pills have the same effect as vitamin C which naturally occurs in fruits and vegetables? Lately we are told that perhaps it does not. How much worse it is when a supplier lies to us about the ingredients in his product! In my view, intentional misrepresentations in this area are ipso facto material because of their inevitable impact upon the victim, which is another way of saying that they need not be proved as part of the government's case.

I believe that the Eighth Circuit's approach to a somewhat similar statute covering misbranded meat products should apply here also. See United States v. Jorgensen, 144 F.3d 550 (8th Cir. 1998). That statute makes it a felony to misbrand meat products with intent to defraud. The court held:

Not requiring a materiality element is also consistent with the public policy underlying the Federal Meat Inspection Act. Congress has determined that the companies and people engaged in the food business have an affirmative duty to insure that the food they sell to the public is safe and properly labeled. Judicially adding a materiality requirement when none exists in the statutory text would not further congressional intent and would instead hinder it.

Id. at 559 (citations omitted). I recognize, of course, that the statute in question there did say that a product is misbranded if the label is "false or misleading in any particular,"<sup>1</sup> and language of that sort does not seem to suggest that materiality is required. Id. That is somewhat more explicit than the lan-

---

<sup>1</sup> See 21 U.S.C. § 601(n)(1).

guage we must consider, but I see it as a distinction without a difference. It would, I expect, stun Congress to hear that it cares a great deal about the meat we ingest, but is rather more insouciant about other food products and drugs.

Moreover, contrary to his argument, Watkins is not aided by 21 U.S.C. § 321(n)'s language.<sup>2</sup> That section provides that in deciding whether something is misbranded in the first place, we must consider exactly what the seller said -- his representations. That makes sense, and here, for example, Watkins said that the product had one ingredient when he knew it had a different one. More than that, however, an additional stringent requirement is placed upon the seller. Once he has made representations about the product, he must go on to give even more information; he must inform buyers as to other facts which are material in light of the representations he did make, and further tell them of any facts which are material to consequences that might flow from the use of the product. That is very far from saying that he can quibble about how material his misrepresentations were in the first place; if they are false, they are false, and that is all. But even if they are technically true, the seller must eschew reliance on the technicality; he must also go on to explain anything that might materially affect the user's perceptions. As I see it, that is even more onerous than a requirement that representations be truthful in all particulars. It means that the seller must be more than truthful; he must be punctilious in assuring that we understand what we are ingesting when we ingest it.

---

<sup>2</sup> In pertinent part § 321(n) reads:

If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested . . . , but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article . . . .

In fine, nothing could shake the foundation of our society more than a fear that people like Watkins can actively and intentionally tell us that we are putting one thing in our bodies when they know we are putting in something else entirely. To let wrongdoers of that kind escape felony penalties through quibbles about whether their intentional lies are material is enough to gally the hardiest souls. It threatens to release the evils of tainted and misbranded food and drugs from the oubliette to which Congress has consigned them. We should not countenance that.

Thus, I respectfully dissent.